



General Law Committee

February 7, 2013

American Cancer Society Cancer Action Network Testimony

HB 5484 - An Act Prohibiting Generic Substitutions For Tamper- Resistant Drug Formulations

Prescription drug abuse is the fastest-growing drug problem in this nation. Certain drugs contain high dose narcotics enclosed in a time-release mechanism that allows it to enter the bloodstream over a pre-determined period of time, usually 12 hours. Drug abusers discovered that by simply crushing the pills, the time-release mechanism was destroyed, enabling the entire dose to be immediately absorbed into the bloodstream.

To combat this abuse, pharmaceutical companies have developed tamper resistant formulations—in essence, drugs that can't be crushed. These new tamper resistant formulations replaced the existing abuse prone formulations, which in turn have been removed from market in the United States.

Data published last year in the New England Journal of Medicine indicate tamper resistant drugs make illicit use more difficult and since introduction, rates of abuse have begun to drop, in some cases, significantly.

However generic drug manufacturers have lobbied for FDA permission to manufacture and market generic versions of the original non-tamper resistant formulations. While in January of this year, the FDA confirmed it has the regulatory authority to require tamper resistant qualities; it has not yet acted on that authority.

In fact, the FDA granted approval of a generic long acting opioid without tamper resistant qualities and is expected to continue to approve additional non-tamper resistant generic medications while reserving the right to enforce its regulatory authority.

As cheaper abuse prone generic formulations begin to flood the market, significant increases in prescription drug abuse will follow.

HB 5484 would prohibit pharmacists and insurance companies from substituting generic drugs for tamper resistant formulation brand name drugs without the consent of the prescribing health care provider.

ACS CAN supports this important, protective measure. Given the specialized nature of cancer care we view the physician-patient decision-making process as a critical component of proper care.